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The Cost-Effectiveness of Home-Based Provision of Antiretroviral Therapy in Rural Uganda

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Abstract

Context—Highly active anti-retroviral therapy (ART) provides dramatic health benefits for HIV-infected individuals in Africa, and widespread implementation of HAART is proceeding rapidly. Little is known about the cost and cost-effectiveness of HAART programs.

Objective—To determine the incremental cost-effectiveness of a home-based HAART program in rural Uganda.

Design, setting and patients—Computer-based, deterministic cost-effectiveness model to assess a broad range of economic inputs and health outcomes. From the societal perspective we compared the cost-effectiveness of HAART and cotrimoxazole prophylaxis with cotrimoxazole alone, and with the period before either intervention. Data for 24 months were derived from a trial of HAART in 1,045 patients in Tororo District in eastern Uganda. Costs and outcomes were projected out to 15 years. All costs are in 2004 U.S. dollars.

Interventions—First-line HAART regimen consisted of standard doses of stavudine, lamivudine, and either nevirapine or, for clients with active tuberculosis, efavirenz. Second-line therapy consisted of tenofovir, didanosine, and lopinavir/ritonavir. For children, first-line HAART consisted of

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Conflict of Interest Statement

All authors declare that they have not conflicts of interest to declare. We will provide signed statements to that effect as needed.

Contributor ship

Elliot Marseille (*First author*): Concept, Design, Parameter estimation, Literature review, Analysis, Writing.

Dr. Marseille had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Ethical approval

No ethical approval was required for this research.

zidovudine, lamivudine and nevirapine syrup; second-line therapy was stavudine, didanosine and lopinavir/ritonavir.

Main outcome measures—HAART program costs, the health benefits accruing to HAART recipients, averted HIV infections in adults and children, and resulting effects on medical care costs.

Results—The HAART program standardized for 1,000 patients cost an incremental \$1.39 million in its first two years. Compared with cotrimoxazole prophylaxis alone, the program reduced mortality by 87%, and averted 6,861 incremental disability adjusted life-years (DALYs). Benefits accrued from reduced mortality in HIV-infected adults, (67.5% of all benefits), prevention of death in HIV-negative children (20.7%), averted HIV infections in adults (9.1%) and children (1.0%), and improved health status (1.7%). The net program cost, including the medical cost implications of these health benefits was \$4.09 million. The net cost per DALY averted was \$597 compared with cotrimoxazole alone. Many HIV interventions have a cost-effectiveness ratio in the range of \$1 – \$150 per DALY averted

Conclusions—A home-based HAART program in rural Africa was more cost-effective than most previous estimates for facility-based HAART programs, but remained less cost-effective than many HIV prevention and care interventions, including cotrimoxazole prophylaxis.

Keywords

HIV/AIDS; antiretroviral drug therapy; cost-effectiveness; economics

1 Background

Anti-retroviral therapy (ART) offers benefits for HIV-infected patients in resource-poor countries that are similar to those reported from industrialized countries. These include reductions in viral load, increases in CD4 cells, reduced incidence of opportunistic infections, decreased mortality, and improvements in well-being and functioning.^(1–6) A three-year home-based HAART trial in rural Uganda demonstrated the feasibility of achieving excellent health outcomes in a rural African setting.¹

In response to worldwide demand and increased funding, implementation of HAART is proceeding rapidly in the developing world, particularly in sub-Saharan Africa.² The expansion of both treatment and prevention activities is a major development in the global response to HIV/AIDS, and HAART provision is a unique global expansion of resource-intensive disease management. In addition to immediate health benefits, HAART provides an opportunity for long-term enhancement of health system capacity.

Understanding the cost and cost-effectiveness of HAART in Africa is important during this period of program expansion,³ to assist in the development and refinement of operational plans that minimize the cost of meeting program goals. More importantly, cost-effectiveness data can help policy-makers allocate resources among an increasing range of prevention, treatment and care options. Indeed, the commitment to treatment reinforces the imperative for effective prevention. Without it, access to treatment becomes more expensive over time, as newly-infected people are added to the millions already on life-time ART. Cost-effectiveness data can shed light on the opportunity cost of various allocation options considered by health policy makers in HIV-affected African countries and by major donors such as the President's Emergency Fund for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, TB and Malaria.

Several cost studies have been completed in Africa.^{4–10}, and four cost-effectiveness studies on facility-based HAART services.^{11–14} Two of these compared HAART with no intervention. However, the appropriate comparison may be with other effective and available care

interventions, such as trimethoprim–sulfamethoxazole (cotrimoxazole) prophylaxis. One study found that HAART was cost-saving for patients with AIDS due to savings in hospitalization and other health expenditures, and cost \$675 per life-year gained for non-AIDS patients. Another found that HAART cost \$1,631 per quality-adjusted life-year (QALY) gained for all treated HIV patients.^{12, 13} A third study that ranked ART's incremental cost-effectiveness against an array of other HIV prevention and treatment options found an incremental cost ranging from \$547 to \$5,175 (international dollars) per disability-adjusted life-year (DALY) averted.¹¹ The 10-fold range of results in this study is due to the multiple incremental program options considered, in which the addition of each successively more costly program element raises incremental costs faster than it raises incremental benefits. Finally, a study using a modification of a previously-published simulation model predicted disease progression and treatment costs as a function of CD4 cell counts and viral loads in a Cote d'Ivoire cohort. This study, which also incorporated appropriate incremental comparisons found ART, when initiated without CD4 testing, to cost \$620 per life-year gained when compared with cotrimoxazole prophylaxis, and \$1,180 per life-year gained if the HAART initiation decision incorporated CD4 test results.¹⁴

This article assesses the cost and cost-effectiveness of HAART when added to a package of home based care (HBAC) provided in a rural district in eastern Uganda. It differs from previously-published studies in a number of respects: there have been no previous empirically-based cost-effectiveness analyses of HAART in Africa outside of South Africa, a middle-income country; and this is the only HAART cost-effectiveness analysis that draws extensively on data from a clinical trial. It is the only study that accounts for the prevention effects of HAART in reducing other family members' mortality and vertical transmission benefits resulting from mothers receiving ART, including both improved health and survival of the child and savings in treatment costs that would otherwise have ensued; and the data derive from a rural, home-based program. Home-based provision of HAART may be particularly appropriate in poor, rural areas where travel to clinics is difficult and costly: it may increase adherence, decrease the number of missed appointments, and enhance the program's ability to monitor for drug toxicity and treatment failure. Use of trained laypersons could also lessen the burden on physicians and nurses and relieve crowding in health centers, but may be more or less costly than clinic-based programs. Demonstrating the potential cost-effective use of non-physician health personnel is particularly important in an era of HAART expansion.¹⁵ Relatively generous HAART funding may otherwise have the unintended effect of drawing scarce highly-trained practitioners away from other effective and cost-effective health care services.

2. Methods

2.1 Setting

Tororo District in eastern Uganda has a population of 403,000, of whom 91% live in rural areas and 46% are unable to meet their caloric requirements. (Uganda Bureau of Statistics, National Household Survey) Eighty percent of the population earns its living by farming. The annual population growth rate is 2.7%.^{16, 17}

2.2 Patients and methods

We studied two sequential cohorts of adults with HIV infection who were clients of the AIDS Support Organization (TASO) in Tororo and Busia Districts, Uganda. The first study, initiated in April of 2001, followed participants for 5 months, then provided daily cotrimoxazole prophylaxis (160 mg of trimethoprim and 800 mg of sulfamethoxazole) and continued follow-up for an additional 1.5 years. For a second study of HAART with cotrimoxazole, initiated in

September of 2001, we enrolled all clinically eligible participants from the first study and additional enrollees for a total of 1,045 participants on ART.¹

Households were visited weekly by study staff who re-supplied medication. After enrollment, participants had no routine clinic visits, but were encouraged to come to the clinic or hospital for signs and symptoms of toxicity or illness, and during the second study were taken to the clinic if they had certain defined symptoms. HIV-infected adults were randomly assigned to three different monitoring regimens: 1) Quarterly CD4 cell counts and HIV viral loads, and weekly home visits by a trained lay person using a standard symptom questionnaire, 2) Quarterly CD4 cell counts and weekly home visits, and 3) weekly visits alone. No other laboratory testing was routinely conducted during follow-up, and serum chemistries were available only just prior to initiating ART. Adherence as measured by pill counts was excellent, with an overall mean of $\geq 99\%$, taken correctly and $< 95\%$ pills taken correctly by only 0.7 – 2.6% of patients in any calendar quarter.¹⁸

2.3 Overview of analytic methods

We developed a computer-based, deterministic cost-effectiveness model implemented in Microsoft Excel®. We incorporated a broad range of economic and health inputs from the societal perspective: HAART program costs, the health benefits accruing to HAART recipients, averted deaths in the HIV-uninfected children of HAART recipients, prevention of mother-to-child transmission, HIV infections averted due to safer sexual behavior and lower plasma viral loads, and the effects of these health benefits on medical care costs.

Calculated costs and health outcomes were used to estimate the incremental cost-effectiveness of HAART added to an ongoing program of cotrimoxazole prophylaxis in the context of a home-based package of basic health services. This package consisted of diagnosis and treatment of diarrhea and malaria, clinical care at the study clinic at Tororo District Hospital, a simple safe water system and educational interventions to improve hygiene. All services were provided to participating individuals free of charge. We divided the period of analysis into two parts: (a) the first 24 months of HAART implementation, for which empirical cost and health outcomes data are available for direct use in the model, and (b) subsequent years, for which we modeled the extended consequences of events occurring during the first period. Markov processes based on one-month cycles and transitions to WHO stages for HIV infection and AIDS were constructed to tabulate the health benefits and medical care costs associated with projection of health consequences beyond the two-year period of the trial. For example, for individuals who averted death due to HAART in the first period, we projected future health benefits and medical costs out 15 years.

Cost-effectiveness is portrayed as net program cost per DALY averted.¹⁹ Model calculations were standardized to 1,000 participants, and all costs and benefits were discounted at a rate of 3% per year.¹⁹

We conducted univariate and bivariate sensitivity analyses to assess the effect of uncertainty on input values. We also conducted a 50,000-trial Monte Carlo simulation to derive a stable estimate of the aggregate uncertainty from all inputs (Crystal Ball,[®] version 7.2). Input estimates were assigned ranges based on reported confidence intervals when available, and otherwise low and high values encompassed likely ranges. Finally, we explored the effect of program implementation scenarios.

Table 1 displays the base case value for all key parameter in the model, the range of values explored in sensitivity analyses, and the sources for these estimates.

2.4 Cost of HAART Program

We conducted a comprehensive accounting of the incremental resources consumed by all ART-related activities and their costs, following standard micro-costing methods.²⁰ Cost data were obtained from the study's expenditure records and interviews with project managers, service delivery staff, and accounting staff. In addition to direct expenditures on HAART provision such as drugs, CD4 cell count and viral load test kits, medical and laboratory personnel time, field staff time and lab supplies, we apportioned administrative and overhead activity costs to the HAART program based on the portion of all program service delivery that is attributable to HAART-related personnel time. This tabulation was performed for both the field office in Tororo District and for headquarters in Entebbe. Time and motion data were collected on all aspects of home visits in order to isolate the specific incremental personnel and supplies costs associated with the HAART-related portion of the home visits including transportation. All costs are in 2004 U.S. dollars converted at 1,750 shillings per dollar. (Cost data collection and time and motion templates available on request from E. Marseille.)

The first-line HAART regimen used in HBAC consisted of stavudine, lamivudine, and either nevirapine or in the 4% of clients with active tuberculosis, efavirenz. We modeled annual costs based on the WHO pre-qualified regimen: stavudine, 150 mg; lamivudine, 40 mg; and nevirapine, 200 mg in fixed-dose combination pills at \$104 per patient-year (Cipla). In cases of early toxicity, zidovudine was substituted for stavudine. Second-line therapy consisted of tenofovir, 300 mg at \$207 per patient-year (Gilead); didanosine, 400 mg at \$288 per patient-year (BMS); and lopinavir/ritonavir (133.3 mg/30 mg) in a fixed-dose combination (Abbott) at \$500 per patient-year for a total of \$995 per patient-year.²¹ For children, a daily regimen of zidovudine, lamivudine and nevirapine in syrup form costs \$143, \$190, and \$256 per year for children under 12 months, 13–24 months, and 25–60 months of age, respectively, based on normal dosing by weight.²² Drug costs assume generic versions manufactured by Cipla Ltd, India.^{21, 22} After five years of age, children switch to adult dosing. Second-line therapy [stavudine (BMS), didanosine (Aurobindo) and lopinavir/ritonavir (Abbott)] costs \$396 per child-year.²³ To reflect international shipping, insurance and handling charges, 12.5% was added to these wholesale drug costs.²⁴

Based on data from HBAC, 1.7% of adult clients required a switch from an NNRTI-based first-line regimen to a second-line regimen with a protease inhibitor over the first two years.

2.5 Health effects of HAART program

Health effects included deaths averted in adults and children, including reduced mortality in HIV-negative children; opportunistic illness averted; HIV infections averted from both horizontal and vertical transmission; and improved quality of life.

2.5.1 Deaths averted—Based on clinical trial data from HBAC, we estimated that the intervention averted 606 adult deaths per 1,000 clients in the first two years. During the first 16 weeks of therapy, observed mortality with HAART in HBAC was 14.4 per 100 years of follow-up, with a hazard ratio of 0.45. This fell to 3.0 per 100 person-years of follow up after week 16 with a hazard ratio of 0.08.²⁵ To derive mortality rates in those without ART, we divided observed mortality by the hazard ratios. We used our model published elsewhere to estimate health benefits after the first two years.²⁶ Mortality for individuals taking second-line HAART, derived from a study conducted in a South-African township, is set at 1.9% per month.¹³ No third-line regimen is available. The model predicts a mean of 9.5 additional years of life (undiscounted), and avoidance of 7.6 DALYs (discounted) for each death averted during the first two years.

In addition, the HBAC trial found a mortality reduction of 78.7% in HIV-uninfected children of HAART clients during the first year. Without data from the second year we assume the same benefit, i.e., 41.9 total in a cohort of 1,000 adult index patients. For each child who otherwise would have died, 33.9 discounted DALYs were averted. This assumes an average age of five at death and a foregone life expectancy of 60

2.5.2 Active tuberculosis episodes—Incidence of active TB fell from 7.27 per 100 person-years during the first six months following initiation of HAART to 2.05 in the next year. This implies the prevention of 52.2 cases per 1,000 clients for the first two years of HAART assuming no further HAART-attributable decline after one year of treatment.

2.5.3 Malaria episodes—Malaria incidence declined with the initiation of HAART from 9.0 to 3.5 cases per 100 person-years of follow-up. This implies the prevention of 110 cases during the first two years of therapy for 1,000 HBAC clients.^{27, 28}

2.5.4 New HIV infections prevented – adults—The program achieved substantial reductions in reported risky sexual behavior and in plasma viral loads. The estimated risk of HIV transmission declined by 98%, from 45.7 to 0.9 per 1,000 person years. The combined effect on HIV transmission eliminated 44.7 cases per 1,000 HBAC HAART patients in the first year.²⁹ Rather than being a continuing annual benefit, most of these averted deaths occur in the first two years, since in the absence of HAART many individuals would die within 2–3 years. Thus, we multiplied this benefit by two to obtain an estimated 88.8 cases prevented, or 86.3 cases prevented after discounting for two years. Using estimates from a Markov model published previously on disease progression in a simulated Ugandan cohort, we found that each HIV infection prevented averted 7.2 DALYs.²⁶ This assumes that all of those who would have become infected would have received ART.

Disability weights for HIV and AIDS were assigned values of 0.135 and 0.505 respectively, based on the Global Burden of Disease Study.^{30, 31} However, since our Markov model is based on WHO stage we interpolated disability weights to assign to WHO stage such that Stage 1 had a disability weight of 0.06, Stage 2 of 0.135, Stage 3 of 0.25 and Stage 4 of 0.505

2.5.5 New HIV infections prevented – infants—We estimated infant HIV infections prevented using data from studies in Africa. A trial in Nairobi, Kenya, reported overall HIV transmission risk at 24 months of 36.7% (95% CI, 29.4 to 44.0).³² The DREAM cohort study (with ART) in Mozambique found a pediatric seroconversion rate of 5.5% at 12 months of age.^{33, 34} These studies together suggest an efficacy of 85%. Breastfeeding rates were similar among HBAC mothers as in these studies, 90%. Importantly, no vertical transmission was found in the HBAC program for mothers on HAART at the time of delivery, which suggests that efficacy may be even higher than 85%. However, we used a conservative 85% efficacy. 65.2 live births occur per year in 1,000 HBAC clients, implying 20.3 cases of pediatric HIV averted in two years ($65.2 \times 0.367 \times 0.85$). We employed a Markov process to track disease progression over 15 years with monthly cycles, and a mortality rate of 2.4% per month for untreated pediatric HIV.³⁵ Assuming a 0.05 disability weight while on ART, each averted pediatric HIV infection averted 14.2 DALYs.

2.5.6 DALYs averted through non-mortality related health benefits—HAART provides health benefits to clients who would have lived through part or all of the first two HBAC years even if they had not received ART. This benefit consists of a return to better health for those in WHO stages 2 – 4, and a reduction in progression for those in stage 1. We assigned maximum disability weight losses, i.e. a return to the health state associated with WHO stage 1 and thus obtained an upper-bound estimate of 0.134 DALYs averted for each client that would not otherwise have died, or 122 DALYs in total.

2.6. Costs associated with health effects

Each health effect described above has cost implications. For example, deaths averted increase costs, since the surviving individuals require treatment. Other health effects lower HIV-related medical costs, e.g., averted opportunistic illnesses and HIV infections.

2.6.1 Cost of HAART saved per adult death averted—We estimated these costs assuming that those whose deaths were averted would have access to an HAART program similar to HBAC. We calculated the cost of deaths averted in adults using our HIV disease state model with costs assigned to future HBAC services, and antiretroviral drugs including changes to second-line drug regimens. The model predicted 7.6 discounted additional years of life entailing \$5,997 in discounted future HBAC program costs for each death averted during years 1–2.^{26, 36}

2.6.2 Cost of HAART saved per adult HIV infection averted—We estimated that the 15-year cost of HAART for new HIV infections is \$7,326, or \$6,320 when discounted to the time of infection.

2.6.3 Savings in HAART costs per infant HIV infection averted—HIV infections averted in infants also result in savings, but with different resource costs and disease progression rates. Two African studies suggest HIV mortality of 40% by 18 months and 46% by month 24, or 2.4 % per month.^{37, 38} Infants initiating HAART immediately after birth would thus experience HIV-related monthly mortality estimated at 0.36% ($[1 - 0.85 \text{ HAART efficacy}] \times 0.024 \text{ monthly HIV mortality}$). Using a monthly switch rate from first to second-line therapies of 1.15 % observed in the HBAC program the resulting discounted medical cost per HIV infection in children is \$6,526 when projected fifteen years.

2.6.4 Cost of TB and malaria cases averted—Based on HBAC program records, the average drug costs for treating TB and malaria cases in HBAC households was \$30.00 and \$7.19 respectively including both adults and children. The cost of Medical Officer visits, screening, lab tests and follow-up are included in the HBAC HAART program costs in this analysis under “personnel”, “recurring goods” and “recurring services”, but were not tabulated separately by disease type.

2.6.5 Hospitalization—The frequency of hospitalization was 43% lower during the period in which patients received HAART and cotrimoxazole than when they received cotrimoxazole alone.²⁵ There were 55.6 hospitalizations per 100 years of follow up in the cotrimoxazole-only period or 1,112 for 1,000 clients over two years. This implies 478.2 hospitalizations averted during two years of the HAART intervention. Each hospitalization episode in this setting lasts an average of 5 days at \$6.26 per day, or \$31.36 per episode.³⁹

2.6.6 Savings in cost of care for deaths averted—Although the 606 deaths averted during the first two years of HAART are associated with future HAART costs, they would also generate savings in medical care costs for terminal illness. We are aware of no data that addresses the question, “What portion of HIV-related opportunistic infection treatment costs are permanently averted rather than merely postponed?” In the absence of relevant data, we set this parameter to a conservative 25% and vary the resulting estimate extensively in the sensitivity analyses. The cost of drugs for treatment of opportunistic infections was found to be \$16.50 per month averaged across all CD4 cell count strata in a study of patients in Cote d’Ivoire before the HAART era.⁴⁰ This ranged from \$6.90 for those with CD4 cell counts > 500 to \$38.00 for those with CD4 cell counts <100. We adopted \$19.15, or half of this high-end estimate as the base case value. A Markov model based on a natural history study set in rural Uganda yields an average life expectancy of 2.6 years for those starting treatment with

cotrimoxazole in WHO stage 3 and 4.^{26, 36} producing a discounted end-of-life medical cost of \$400 per death averted (range \$50 to \$750).

3. Results

3.1 ART Program Costs

The incremental cost of the HBAC program was \$1.39 million per 1,000 clients in its first two years (Table 2). Personnel expenditures were the single largest cost followed by the antiretroviral drugs (Figure 1). Antiretroviral drugs constituted 22.1% of the total and \$171 per adult client-year during the first two years of treatment. These figures reflect a preponderance of first line ARV regimens; per-client ARV costs would increase over time as more clients require expensive second-line regimens.

3.2 Health benefits

The program averted 6,791 incremental DALYs due to health benefits observed in its first two years (Table 2). The largest portion (67.5%) of these benefits stem from mortality reduction due to ART. The prevention of death in 41.9 HIV-negative children accounted for 20.7% of total program benefits. HIV cases prevented through reductions in risky behavior and per-episode transmission risk is the third largest benefit, comprising 9.1% of the total. The 20.3 HIV cases averted among infants account for 1.0% of the total health benefit. See Figure 2.

3.3 Costs adjusted for health benefits

The program cost would rise to \$5.02 million when including the discounted future costs of HAART for individuals with deaths averted during the first two years. See Table 2. The net cost is reduced to \$4.09 million by adjusting for the saved costs of opportunistic infections prevented and of HAART for HIV cases prevented.

The incremental net cost per DALY averted is \$597 (\$4.09 million/6,861).

3.4 Sensitivity Analyses

3.4.1 One-way sensitivity analyses—Figure 2 displays the effect of the most influential input variables on the incremental cost-effectiveness of HBAC as these variables assume the ranges shown in Table 1. The twelve most important determinant of cost-effectiveness are the variables governing the DALYS averted per HIV-related death averted by the HBAC program. The next most influential variable is the number of new HIV infections that would have occurred absent the prevention benefits of the HAART program. As it varies from 50% to 150% of its base case value, 45.7 per 1,000 clients (Table 1), the cost per DALY averted varies by 9% to the upside and 8% to the downside. Other variables have less influence on cost-effectiveness. The cost of first-line antiretroviral drugs affect the cost effectiveness ratio by 7% to the upside (less favorable cost effectiveness) as drug costs increase by 50% and 7% to the downside as costs decrease by 50%.

3.4.2 Scenario analyses—A reduction in second-line drug costs of 75% reduced the cost per DALY averted from \$597 to \$572, only 4%. This low sensitivity was due to the low rates of required regimen switching in HBAC. Data from non-African settings found that 15% of clients require change to a second-line regimen annually.^{41–43} A 15% rate of regimen change would increase the cost per DALY averted to \$779, an increase of 30.5%.

We optimistically assumed that 100% of the population even outside HBAC has access to ART. This assumption increases both costs and benefits, and so has little effect on cost-effectiveness. If only 50% of the population had access, the cost per DALY averted would rise by \$2.

3.4.3 Multivariate sensitivity analysis—A Monte Carlo simulation assessed the aggregate uncertainty from all varied inputs. In the absence of information about the distribution of input values, beta distributions with maximum and minimum values set to 50% and 150% of the base case value were fit around each variable of interest. The alpha and beta parameters were set to 3, ensuring a symmetrical distribution approximating the normal with the base case as the mean value.⁴⁴ With 50,000 trials, the incremental cost of the HBAC program varied between \$3.75 and \$4.39 million at the 80% confidence level and DALYs averted varied between 5,610 and 8,141. The 80% confidence interval for HBAC's cost-effectiveness is \$490 to \$737 per DALY averted. Because we did not have the data to match distribution types and parameters values to underlying data characteristics, we re-ran the simulation assuming uniform distributions. This provides a measure of how sensitive results are to the choice of distributions and their central tendencies. With uniform distributions, the cost per DALY averted varied from \$440 to \$846 at the 80% confidence level, an increase in the range of 61% (\$490 – \$737 versus \$440 – \$846).

4. Discussion

This analysis estimates that home-based HAART costs \$597 per DALY averted when compared incrementally with cotrimoxazole prophylaxis in conjunction with basic care. We accounted for a wide range of benefits, including sharply abated risk for HIV transmission through behavioral counseling and lowered viral loads, reduced mortality in HIV-uninfected children, and prevention of mother-to-child transmission of HIV.

With current ARV prices, cost-effectiveness becomes less favorable as more clients require second-line drugs. Yet ARV costs are likely to decline. The William J. Clinton Foundation has negotiated lower second-line prices.⁴⁵ First-line regimen costs may also drop. Nonetheless, even if all ARV costs were to decline by 50%, the cost per DALY averted through HBAC would decline by only about 13%. Even with drug costs at zero, program cost effectiveness would still be \$451 per DALY averted. Dramatic gains in overall cost-effectiveness will therefore not arise from further drug cost reductions alone. In part, this modest net effect is due to the decreased future savings associated with HAART-related prevention if drugs costs decline.

Similarly, since adherence in the HBAC program approaches 100 percent, major gains in cost-effectiveness are unlikely to derive from improvements in clinical benefits. Instead, program managers seeking higher efficiencies face the broader challenge of identifying savings across a range of resource inputs, and doing so without undermining program benefits. Savings could include greater personnel productivity, streamlined monitoring, and efficiencies with prevention programs. For HBAC, cost reductions might be possible through reduced home visits, though such adjustments must be accompanied by adherence monitoring to assure no substantial loss in effectiveness.

This analysis has several limitations. It is based on empirical data from only two years. Other uncertainties arise from the use of data on disease progression and disability weights from published literature. Sensitivity analyses suggest that plausible ranges in these parameters would not substantially change the results. Further, we did not account for toxic drug reactions, thus slightly underestimating the costs and over-estimating the benefits of ART. Similarly, we did not account for the increased longevity of HBAC clients and the accompanying greater duration of risk of HIV transmission. We also did not attempt to estimate the effect of reduced TB incidence in HBAC households on TB incidence in the wider community. Including such an estimate would yield a slightly more favorable cost-effectiveness result.

We did not consider community disinhibition effects on HIV risk behavior, for which we have no data. There is evidence from non-African settings of this phenomenon.^{41, 46–49} Epidemic models suggest that disinhibition could reduce or eliminate the benefits of ART, and increase HAART costs as more individuals become infected.^{42, 50} However, we are encouraged by the sharp reduction in HIV risk suggested for the HBAC client population. This risk reduction in positives may counteract potential risk increases in the general community. More optimistically, the observed risk reduction in clients may be an indicator of the community reaction to ART, through disease destigmatization and enhanced risk reduction messages.

The cost-effectiveness of HAART in our analysis is less attractive than the cost-effectiveness of facility-based HAART found in Cape Town, South Africa, for individuals with AIDS (WHO Stage 4) probably due to that study's non-incremental approach and high savings for opportunistic infections.¹² Our estimate is more favorable for WHO Stages 2–3, reflecting inclusion of a broader set of benefits. Our result is also more favorable than the \$1,631 per QALY found for facility-based HAART services in a South African township,¹³ due to the higher cost of both first and second-line ARV regimens in that study, the higher rates of transition from first to second line therapy, and the omission of other benefits. In spite of these variations, all three studies found cost-effectiveness within the broad range presented as reasonable for east Africa (\$575 to \$5,175 for incremental comparisons, \$556 to \$2,010 versus no intervention). If the novel horizontal transmission benefits and the reduced mortality of HIV-uninfected children were excluded from this analysis, the cost-effectiveness ratio would become less favorable, rising from \$597 per DALY, to \$963 per DALY, placing our results roughly in the middle of the range of results found in these facility-based HAART programs.

Our finding that the economics of home-based HAART distribution in poor rural areas compares favorably with facility-based HAART^{12, 13} has significant program and policy implications. Because the HBAC program uses trained lay people and no scheduled clinic visits, it demonstrates a successful attempt to use allied health workers in HIV care. The use of non-physicians for HIV care delivery is important as considerable constraints on access stem from limited availability of human resources, including physicians.

Apart from the extensive use of non-MDS, the program of weekly home visits is resource-intensive. Other programs could use less frequent visits, or could reduce frequency over time, perhaps contingent on the establishment of good adherence. The complex trade-offs between program operational costs, health benefits and secondary program costs incurred if, for example clients switched to second line therapy at higher rates, were not considered in this analysis.

5. Conclusion

At \$597 per DALY averted, HAART in rural Uganda is less cost-effective than several other well-accepted HIV care and prevention interventions. Many HIV and non-HIV public health interventions have a cost-effectiveness ratio in the range of \$1 – \$150 per DALY averted. These include standard childhood immunization costs (\$1–\$5 per DALY); INH prophylaxis (\$25 per DALY; cost saving if counting secondary transmission); peer HIV prevention education for sex workers (\$4 – \$7 per DALY); adult male circumcision (\$12 per DALY and cost-saving if averted HIV treatment costs are included).^{11, 30, 51–54} HAART provision is also less cost-effective than cotrimoxazole delivered in the same setting, which may be cost-saving.³⁹ Therefore, from an economic point of view expenditures on HAART are questionable while there remains a large unmet need for these more cost-effective alternatives. Nevertheless, to reduce mortality in individual patients, clinicians, countries and donors are committed to the rapid expansion of HAART in sub-Saharan Africa and other resource-poor settings. Given this commitment, home-based delivery of HAART and basic care and prevention services may be

an efficient and relatively cost-effective model for providing care to HIV-infected people living in rural settings.

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Figure 1. Breakdown of HAART two-year program costs by major expenditure categories. Overhead and administration account for 11.1% of total costs, and have been allocated to each of the six categories shown. All incremental program costs are included such as the HAART-related portion of personnel, transportation and supplies associated with home visits.

Figure 2.

Source of disability-adjusted life-years averted by HBAC clients, their HIV-negative children and future case prevented.

Figure 3.

Univariate sensitivity analyses: Variation in incremental cost-effectiveness as the most influential variables assume values across the ranges specified in Table 1. The base case cost-effectiveness is \$597 per DALY averted, which is obtained when input variables are at their 50-percentile (base case) value shown in Table 1.

Table 1

Base case model input values, ranges used in sensitivity analyses and data sources. HAART drug costs reflect generic prices, rather than the higher procurement costs borne by the HBAC program.

	Base case	Range	Source
General			
Number of (standardized) clients	1000	-	-
Population access to HAART	100%	50% ¹	Assumption
Discount rate	3%	2% – 4%	World Bank, 1993
Annual rate of regimen change (1st line to 2nd line)	1.7%	0% – 15.0%	HBAC program records
Health-related quality of life (“utility”) by WHO stage			
Disability weight: WHO stage 1	0.06		Mathers, 2004; Jamison, 2006; Authors’ construction
Disability weight: WHO stage 2	0.14		
Disability weight: WHO stage 3	0.25	95% – 105% ²	
Disability weight: WHO stage 4	0.51		
Program cost per 1000 individuals receiving HAART (Two years)			
Personnel	\$545,882	50% – 150%	HBAC program records
ARV drugs	\$306,469	-	
Annual cost of 1st-line regimens at treatment start; per client	\$125	50% – 150%	MSF, 2007
Annual cost of 2nd-line regimen per client	\$1,119	50% – 150%	
Other recurrent goods	\$341,125		
Recurrent services	\$45,640	-	
Equipment	\$143,485	-	HBAC program records
Buildings	\$4,068	-	
Cost of care for illness episodes prevented			
Death	\$400	50% – 150%	Assumption
TB episode	\$30	50% – 150%	HBAC program records
Malaria episode	\$7.19	50% – 150%	HBAC program records
Hospitalization (survive)	\$31.36	50% – 150%	Pitter, 2007
Health Benefits			
Illness episodes and care averted			
Deaths averted in adults (per 1000 individuals)	606		HBAC program records
HAART efficacy: mortality reduction in HIV-neg. children	79%	75% – 125%	HBAC program records
DALYs averted per childhood death averted (discounted)	33.9		Authors’ construction; Murray, 1994
Life-years added per death averted (undiscounted)	9.5		Morgan, 1997; Marseille, 2006
DALYs averted per death averted (discounted)	7.6	50% – 150%	Calculated from life years
TB new active cases (per 1000 individuals)	52.2	50% – 150%	HBAC program records
Malaria episodes (per 1000 individuals)	110	50% – 150%	HBAC program records
Hospitalizations (survive; per 1000 individuals)	478.2	50% – 150%	HBAC program records

	Base case	Range	Source
Non-mortality related health benefits			
Cases that would not have been fatal absent HAART (per 1000 individuals)	906	50% – 150%	HBAC program records
DALYs averted per case	0.13	50% – 150%	Authors' construction
Cost of care for HIV infections prevented			
Adult's lifetime cost of treatment (discounted)	\$7,326	50% – 150%	Morgan, 1997; Marseille, 2006; MSF, 2007 Authors' construction, HBAC records, MSF, 2007
Infant's lifetime cost of treatment (discounted)	\$6,526	50% – 150%	
New adult HIV infections prevented			
Infections expected per 1000 HIV- infected individuals per year absent HAART	45.7	50% – 150%	HBAC program records
Two-year number expected from 1000 HIV-infected individuals per year	1.3		Authors' construction
Multiplier to reflect additional cases prevented after year 2	2	50% – 150%	Authors' construction
Year when the non-year 1 HIV infections averted would have occurred	2	50% – 150%	Assumption
DALYs averted per HIV infection prevented	7.2	50% – 150%	Authors' construction
Mother-to-child-transmission prevention			
Live births per 1000 female HBAC clients	32.6	50% – 150%	HBAC program records
Late background MTCT rate	0.37	50% – 150%	Nduati, 2000
HAART effectiveness for MTCT	0.85	50% – 150%	Palombi, 2006
Infant cases averted	20.3	50% – 150%	Authors' construction
DALYs averted per averted case of infant AIDS (discounted)	3.4	50% – 150%	Authors' construction

¹ 50% population access to HAART used in one-way sensitivity analysis only.

² This and all remaining ranges below refer to relative percent variation of base case values.

Table 2

HBAC HAART program: Incremental costs, benefits and cost-effectiveness results over two years.

Costs, health benefits and cost-effectiveness	
Program cost for 1,000 clients	\$1,386,670
Cost of ART for deaths prevented	\$3,634,353
Program cost plus costs of HAART for deaths prevented in first two years	\$5,021,023
Savings in opportunistic infection treatment costs	(\$247,750)
Cost net of opportunistic HIV infections prevented	\$4,773,273
Savings in new infant and adult HIV cases prevented	(\$677,815)
Cost net of illness and new adult and infant HIV infections prevented	\$4,095,458
DALYs averted (deaths and infections prevented; incl. deaths prevented in HIV-neg. children)	6,791
DALYs averted through MTCT	70
Total DALYs averted	6,861
Net cost per DALY averted	\$597